swissmedic

Summary report on authorisation dated 24 March 2026

Carvykti® (active substance: ciltacabtagene autoleucel)

Indication extension in Switzerland: 21 October 2024

Dispersion for infusion for the treatment of adults with relapsed and refractory multiple myeloma

About the medicinal product

Carvykti contains the active substance ciltacabtagene autoleucel.

Swissmedic first authorised Carvykti on 8 August 2022 for the following indication: Treatment of advanced multiple myeloma ("bone marrow cancer") in adults whose multiple myeloma (MM) has not responded to at least three previous treatments (refractory), and who have demonstrated disease progression after the last treatment (relapsed).

As a result of this indication extension, Carvykti can be used to treat adults with recurrent and refractory multiple myeloma who have received at least two previous treatments and not responded sufficiently to lenalidomide.

MM is a rare form of cancer that accounts for around 1-2% of all cancers. The frequency of new cases of MM increases with age. Two thirds of new sufferers are aged over 65. The disease is characterised by excessive replication of plasma cells, a type of white blood cell responsible for producing antibodies in the body's defence system (immune system). In MM, plasma cells multiply in an uncontrolled way in the bone marrow and occasionally in other organs as well. This prevents normal blood cell formation and can destroy, or disrupt the function of, bones and other organs.

Since multiple myeloma is a rare, life-threatening disease, Carvykti has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

Ciltacabtagene autoleucel, the active substance in Carvykti, is an immunotherapy that uses genetically modified autologous[1] T cells. This therapy uses patients' own T cells that have been modified so that they can recognise and fight B cell maturation antigen (BCMA) on the surface of myeloma cells. When the modified T cells are reintroduced into the body, they bind to the cancer cells and help destroy them.

Administration

Carvykti is a prescription-only medicine.

It is administered intravenously (into a vein) as an infusion and contains 0.5–1.0 x 10^6 CAR-positive viable T cells per kg body weight, with a maximum dose of 1 x 10^8 CAR-positive viable T cells. The recommended treatment comprises a single infusion of Carvykti administered in a qualified treatment centre under the supervision and guidance of a doctor.

Efficacy

The efficacy of Carvykti was investigated in study MMY3002. This study compared Carvykti with the standard treatment in patients with multiple myeloma who had previously received at least one line of treatment. 208 participants received Carvykti, while 211 received a standard treatment. The results showed that the disease did not progress in patients who had received Carvykti for significantly longer than in patients who received the standard treatment. In addition, more patients responded well to the treatment.

Precautions, undesirable effects, & risks

Carvykti must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects (affecting more than 60% of patients) were blood count abnormalities such as low white blood cell count (neutropenia), anaemia (lack of red blood cells), thrombocytopenia (low blood platelet count), cytokine release syndrome[2] and fever.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

[1] Autologous: belonging to the same person, i.e. the patient's own T cells in this case

[2] Cytokine release syndrome: Cytokine release syndrome is a systemic inflammatory response to the massive secretion of cytokines (proteins), which activate the white blood cells.

Why the medicinal product has been authorised

Patients with relapsed and refractory multiple myeloma who have received at least two lines of treatment, including an immunomodulator, a proteasome inhibitor, and an anti-CD38 antibody, and who do not respond adequately to lenalidomide have only limited treatment options.

Carvykti offers this group of patients a further treatment option that specifically kills off the cancer cells.

The results of the study show a higher response rate and sustained effectiveness, with the majority of patients experiencing no disease progression for a protracted period.

While the medicinal product can have potentially severe side effects, the severity of these can be mitigated by close monitoring and timely intervention. Overall, the positive effects of Carvykti on the health and quality of life of patients outweigh the known risks. Based on these findings, Swissmedic has authorised the medicinal product Carvykti in Switzerland for the treatment of adults with relapsed and refractory multiple myeloma who have received at least two previous therapies and are refractory to lenalidomide.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Carvykti®

Information for patients (package leaflet): Information for patients Carvykti®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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